interval for CR OXY relative to IR OXY relative was 89.5% - 115.9% for AUC (0,36) and 92.9% - 121.9% for AUC (0,∞). Based on the 90% confidence interval analysis, the controlled-release oxycodone tablets were equivalent in extent of absorption (AUC 0,36) to the immediate-release oxycodone solution. The controlled-release oxycodone absorption was slower by approximately 1.3 hours. No statistically significant differences were noted between the two treatments with reference to adverse experiences, none of which were considered clinically unusual for opiates for this type of study.

The above studies demonstrate a significant dose-response relationship utilizing the controlled release oxycodone formulations of the present invention at dosages of 10, 20 and 30 mg which does not deviate from parallelism with dose-response slopes for MS Contin in similarly designed well-controlled analgesic efficacy studies of MS Contin reported by Kaiko R.S., Van Wagoner D., Brown J., et al., "Controlled-Release Oral Morphine (MS Contin® Tablets, MSC) in Postoperative Pain.", Pain Suppl., 5:S149 1990, who compared 30, 60, 90, and 120 mg of MS Contin as compared with 10 mg of intramuscular morphine and placebo and Bloomfield, et al., "Analgesic Efficacy and Potency of Two Oral Controlled-Release Morphine Preparations", Clinical Pharmacology & Therapeutics, (in press), who compared 30 and 90 mg of MS Contin as compared to 30 and 90 mg of another controlled-release oral morphine preparation, Oramorph SR 30 mg tablets.

The examples provided above are not meant to be exclusive. Many other variations of the present invention would be obvious to those skilled in the art, and are contemplated to be within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone, based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, said formulation providing a desired analgesic effect for at least about 12 hours.

2. The controlled release oxycodone formulation of claim 1, comprising from about 10 to about 40 mg oxycodone based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration.

3. The controlled release oxycodone formulation of claim 1, comprising from about 40 mg to about 160 mg oxycodone based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration.

4. The solid controlled release oxycodone formulation of claim 1, comprising

oxycodone hydrochloride dispersed in an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing, and a suitable amount of a suitable pharmaceutical diluent.

5. The solid controlled release oxycodone formulation of claim 1, comprising:

(a) an analgesically effective amount of spheroids comprising oxycodone or a salt thereof and either a spheronising agent or an acrylic polymer or copolymer, such that the total dosage of oxycodone in said dosage form is from about 10 to about 160 mg based on the hydrochloride salt; and

(b) a film coating on said spheroids which controls the release of the oxycodone or oxycodone salt at a controlled rate in an aqueous medium, wherein said composition provides an in vitro dissolution rate of the dosage form.

6. The controlled release oxycodone formulation of claim 1, comprising a tablet wherein said oxycodone is dispersed in a controlled release matrix.

7. The controlled release oxycodone formulation of claim 1, wherein said oxycodone is in the form of the hydrochloride salt.

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8. A method for substantially reducing the range in daily dosages required to control pain human patients, comprising administering an oral controlled release dosage formulation comprising from about 10 to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration.

9. A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 10 mg to about 40 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of up to about 2 to about 4.5 hours after administration.

10. A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 40 mg to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration.

08/618,344

ABSTRACT OF THE DISCLOSURE

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions. Another embodiment is directed to a method for substantially reducing the range in daily dosages required to control pain in substantially all patients by administering an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof, such that a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions are achieved. Controlled release oxycodone formulations for achieving the above are also disclosed.

PRINT OF DRAWINGS
AS ORIGINALLY FILED

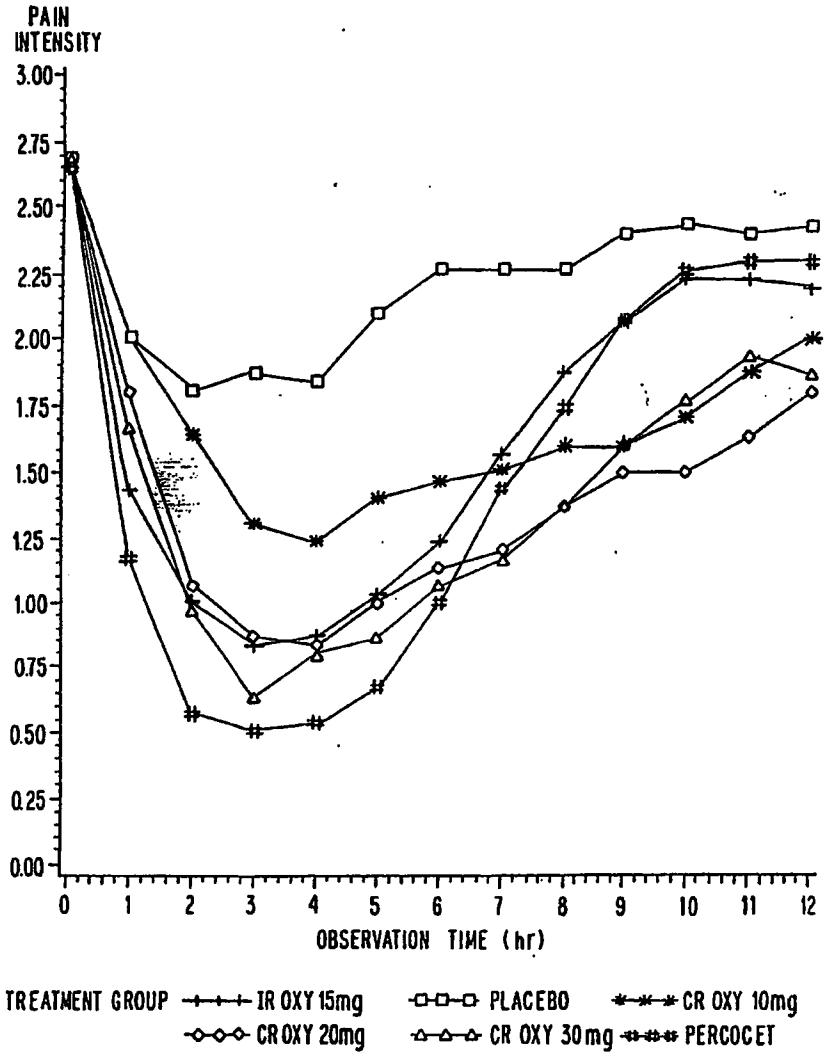

FIG. 1

PRINT OF DRAWINGS
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08/618344

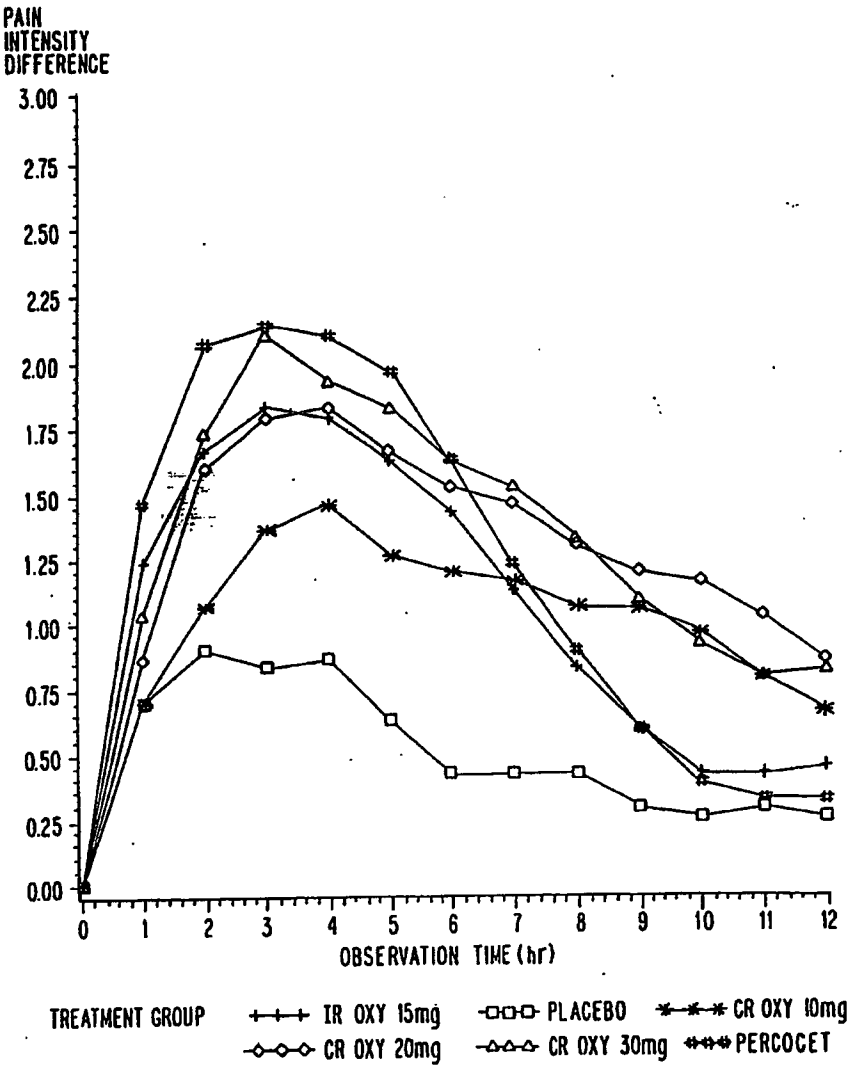

FIG.2

'295 - 47

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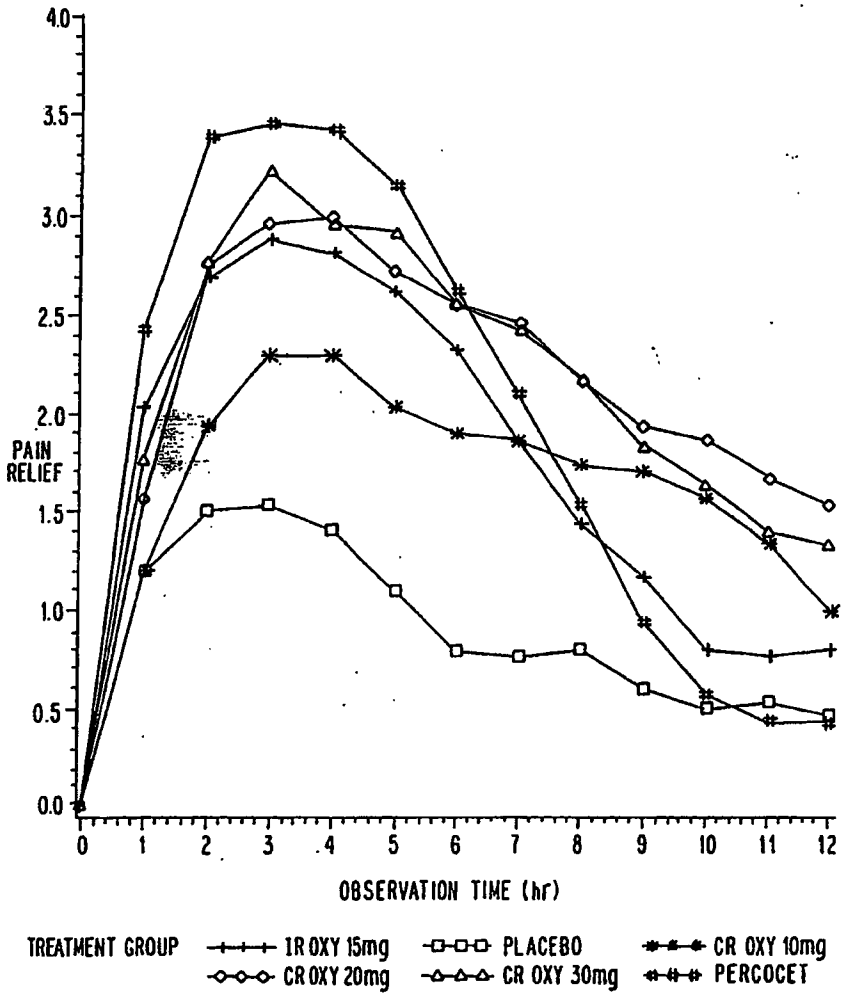

FIG. 3

PRINT OF DRAWINGS
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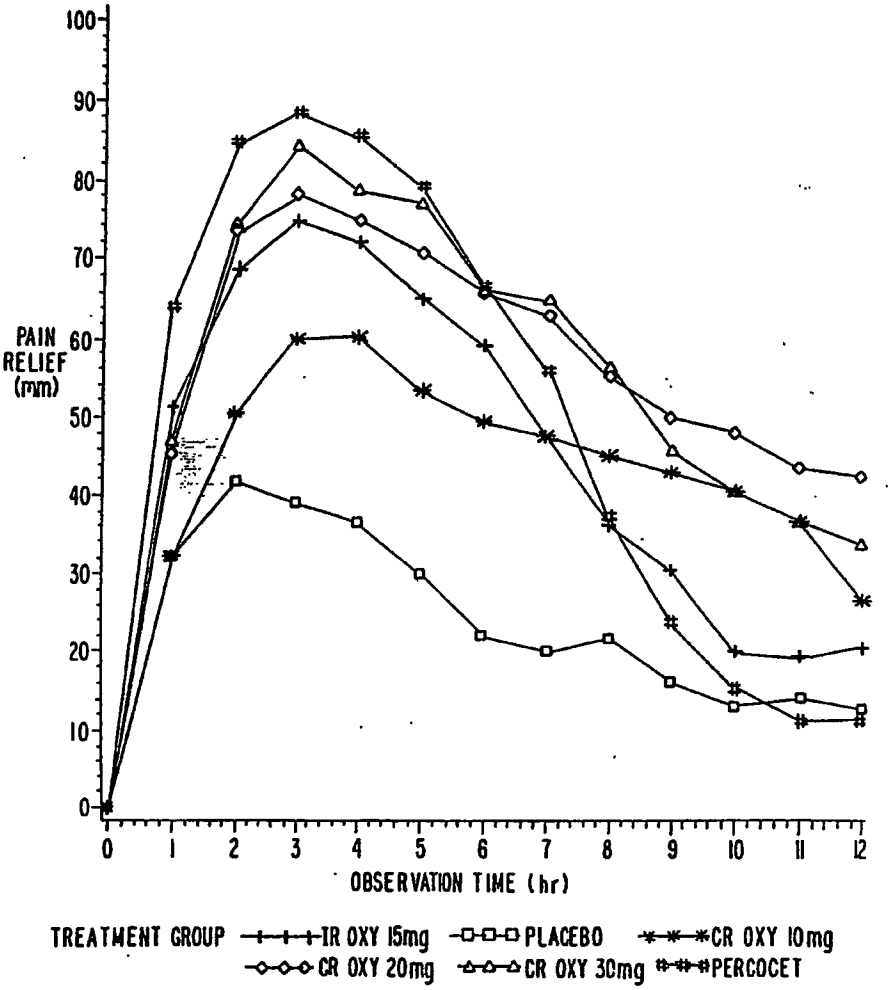

FIG. 4

PRINT OF DRAWINGS
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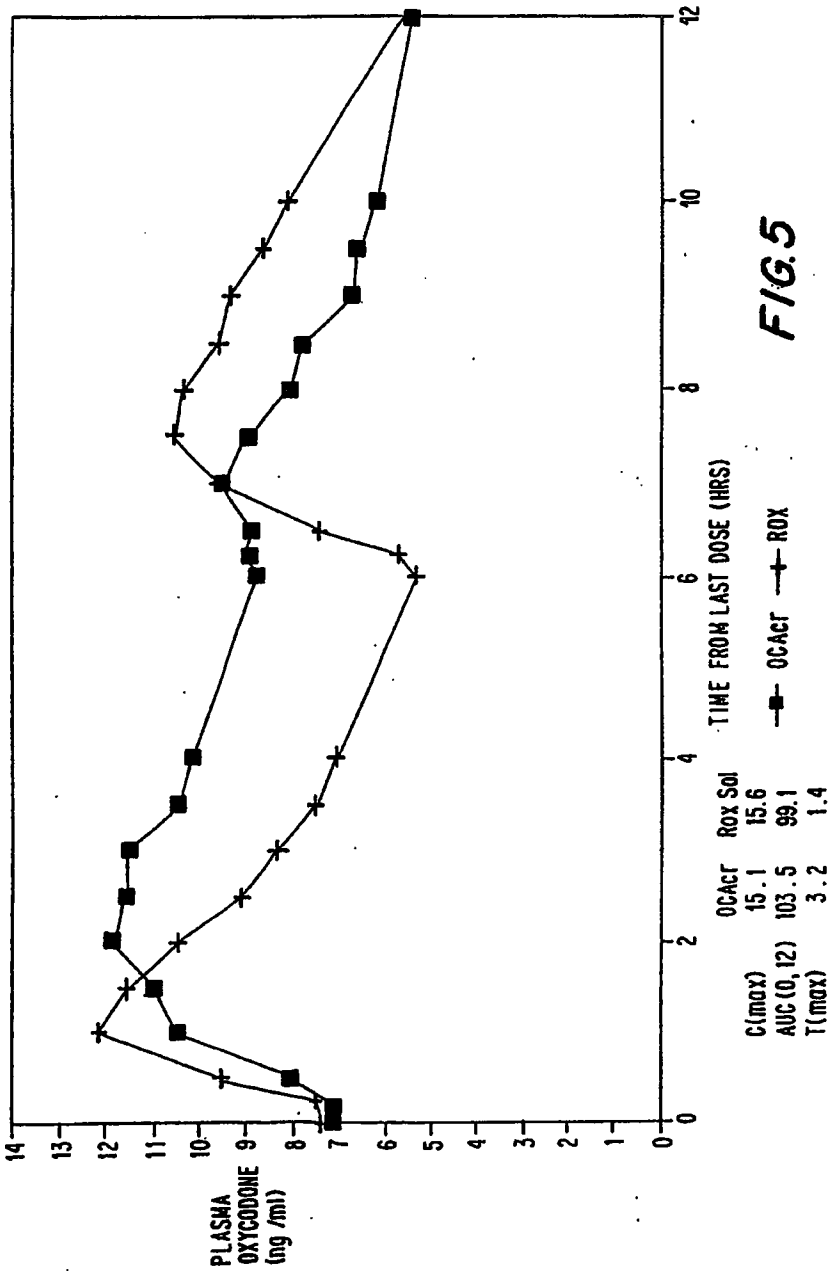

FIG.5

'295 - 50

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/[illegible],344	03/19/96	OSHLACK	B 200.9331-1CON

0252/0503

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

0000

DATE MAILED: 05/03/96

NOTICE TO FILE MISSING PARTS OF APPLICATION
FILING DATE GRANTED

An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted **ALONG WITH THE PAYMENT OF A SURCHARGE** for items 1 and 3-6 only of $ 130 for large entities or $ 65 for small entities who have filed a verified statement claiming such status. The surcharge is set forth in 37 CFR 1.16(e).

If all required items on this form are filed within the period set below, the total amount owed by applicant as a ☑ large entity, ☐ small entity (verified statement filed), is $ 130.

Applicant is given **ONE MONTH FROM THE DATE OF THIS LETTER, OR TWO MONTHS FROM THE FILING DATE** of this application, **WHICHEVER IS LATER**, within which to file all required items and pay any fees required above to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

1. ☐ The statutory basic filing fee is: ☐ missing ☐ insufficient. Applicant as a ☐ large entity ☐ small entity, must submit $________ to complete the basic filing fee.

2. ☐ Additional claim fees of $________ as a ☐ large entity, ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

3. ☑ The oath or declaration:
   ☑ is missing.
   ☐ does not cover items omitted at time of execution.

   An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date is required.

4. ☐ The oath or declaration does not identify the application to which it applies. An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

5. ☐ The signature(s) to the oath or declaration is/are: ☐ missing; ☐ by a person other than the inventor or a person qualified under 37 CFR 1.42, 1.43, or 1.47. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

6. ☐ The signature of the following joint inventor(s) is missing from the oath or declaration:
   __________ An oath or declaration listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

7. ☐ The application was filed in a language other than English. Applicant must file a verified English translation of the application and a fee of $________ under 37 CFR 1.17(k), unless this fee has already been paid.

8. ☐ A $________ processing fee is required since your check was returned without payment. (37 CFR 1.21(m)).

9. ☐ Your filing receipt was mailed in error because your check was returned without payment.

10. ☐ The application does not comply with the Sequence Rules. See attached Notice to Comply with Sequence Rules 37 CFR 1.821-1.825.

11. ☐ Other.

Direct the response and any questions about this notice to, Attention: Application Processing Division, Special Processing and Correspondence Branch (703) 308-1202.

A copy of this notice MUST be returned with the response.

'295 - 51

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/618,344	03/19/96	OSHLACK	B 200.93311CON

0252/0506

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

0000

DATE MAILED: 05/06/96

NOTICE TO FILE MISSING PARTS OF APPLICATION
FILING DATE GRANTED

An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted **ALONG WITH THE PAYMENT OF A SURCHARGE** for items 1 and 3-6 only of $ 130 for large entities or $ 65 for small entities who have filed a verified statement claiming such status. The surcharge is set forth in 37 CFR 1.16(e).

If all required items on this form are filed within the period set below, the total amount owed by applicant as a ☑ large entity, ☐ small entity (verified statement filed), is $ 130.

Applicant is given ONE MONTH FROM THE DATE OF THIS LETTER, OR TWO MONTHS FROM THE FILING DATE of this application, WHICHEVER IS LATER, within which to file all required items and pay any fees required above to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

1. ☐ The statutory basic filing fee is: ☐ missing ☐ insufficient. Applicant as a ☐ large entity ☐ small entity, must submit $_____ to complete the basic filing fee.

2. ☐ Additional claim fees of $_____ as a ☐ large entity, ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

3. ☑ The oath or declaration:
   ☑ is missing.
   ☐ does not cover the newly submitted items.

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4. ☐ The oath or declaration does not identify the application to which it applies. An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

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9. ☐ Your filing receipt was mailed in error because your check was returned without payment.

10. ☐ The application does not comply with the Sequence Rules. See attached Notice to Comply with Sequence Rules 37 CFR 1.821-1.825.

11. ☐ Other.

Direct the response to Box Missing Part and refer any questions to the Customer Service Center at (703) 308-1202.

A copy of this notice MUST be returned with the response.

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'295 - 52

130-105 Loc 0310

200.93311.CON

PAT. & TRADEMARK OFF. 1996 Rec.

UNITED STATES PATENT & TRADEMARK OFFICE

Application of:	Benjamin OSHLACK, Mark CHASIN, John J. MINOGUE, and Robert F. KAIKO
Serial No.:	08/618,344
Filed:	March 19, 1996
For:	CONTROLLED RELEASE OXYCODONE COMPOSITIONS

RESPONSE TO NOTICE TO FILE MISSING PARTS

Hon. Commissioner of
Patents and Trademarks
Washington, D.C. 20231

May 23, 1996

Sir:

In response to the Notice to File Missing Parts dated May 6, 1996, enclosed please find an executed Declaration and Power of Attorney form and a check in the amount of $130.00 covering the surcharge.

If any additional fees are deemed to be due at this time, the Commissioner is authorized to charge payment of the same to Deposit Account No. 19-4210. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
STEINBERG, RASKIN & DAVIDSON, P.C.

By Clifford M. Davidson by James R. Crawford Reg. No 39,155
Clifford M. Davidson
Reg. No. 32,728

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner of Patents and Trademarks, Washington, D.C. 20231" on May 23, 1996.
STEINBERG, RASKIN & DAVIDSON, P.C.
BY: James R. Crawford Reg No 39,155

'295 - 53

MAIL ROOM MAY 23 PAT. & TRADEMARK OFF.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/618,344	03/19/96	OSHLACK	B 200.93311CON

0252/0506

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

0000

DATE MAILED: 05/06/96

NOTICE TO FILE MISSING PARTS OF APPLICATION
FILING DATE GRANTED

An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted **ALONG WITH THE PAYMENT OF A SURCHARGE** for items 1 and 3-6 only of $ 130 for large entities or $ 65 for small entities who have filed a verified statement claiming such status. The surcharge is set forth in 37 CFR 1.16(e).

If all required items on this form are filed within the period set below, the total amount owed by applicant as a ☑ large entity, ☐ small entity (verified statement filed), is $ 130.

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   ☑ is missing.
   ☐ does not cover the newly submitted items.

   An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date is required.

4. ☐ The oath or declaration does not identify the application to which it applies. An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

5. ☐ The signature(s) to the oath or declaration is/are: ☐ missing; ☐ by a person other than the inventor or a person qualified under 37 CFR 1.42, 1.43, or 1.47. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

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8. ☐ A $_____ processing fee is required since your check was returned without payment. (37 CFR 1.21(m)).

9. ☐ Your filing receipt was mailed in error because your check was returned without payment.

10. ☐ The application does not comply with the Sequence Rules. See attached Notice to Comply with Sequence Rules 37 CFR 1.821-1.825.

11. ☐ Other.

Direct the response to Box Missing Part and refer any questions to the Customer Service Center at (703) 308-1202.

A copy of this notice MUST be returned with the response.

COPY TO BE RETURNED WITH RESPONSE

FORM PTO-1533 (REV. 11-94)

'295 - 54

MAIL ROOM 62 MAY 28 1996 PAT. & TRADEMARK OFF.

Docket No.: 200.93311.CON

U.S.A.
DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CONTROLLED RELEASE OXYCODONE COMPOSITIONS the specification of which (check one) __ is attached hereto
X was filed on March 19, 1996 as Application Serial No. 08/618,344 and was amended on _____ (if applicable).
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.
I acknowledge the duty to disclose all information which is known to me to be material to the patentability of this application as defined in Title 37, Code of Federal Regulations, §1.56.
I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN APPLICATION(S)			Priority claimed..	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

08/081,302 (Application Serial Number)	06/18/1993 (Filing Date)	Pending (Status) (patented, pending, abandoned)
07/800,549 (Application Serial Number)	11/27/1991 (Filing Date)	Patented as U.S. Patent No. 5,266,331 on 11/30/93 (Status) (patented, pending, abandoned)
PCT/US92/10146 (Application Serial Number)	11/25/1992 (Filing Date)	Pending (Status) (patented, pending, abandoned)

And I hereby appoint Martin G. Raskin, Registration No. 25,642, Clifford M. Davidson, Registration No. 32,728, Michael N. Mercanti, Registration No. 33,966, Laurence Manber, Registration No. 35,597, Brian Roffe, Registration No. 35,336, Leslye B. Davidson, Registration No. 38,854 and James R. Crawford, Registration No. 39,155 my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith; correspondence address: STEINBERG, RASKIN & DAVIDSON, P.C., 1140 Avenue of the Americas, New York, N.Y. 10036; Telephone: (212) 768-3800; Fax: (212) 382-2124.
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00

Full name of sole or first Inventor Benjamin OSHLACK
Inventor's signature Benjamin Oshlack
Date 22 May 1996
Residence (city) New York, (state or country) New York NY
Citizenship Australia
Post Office Address 351 East 84th Street, New York, New York, 10028, United States of America

2-00

Full name of joint Inventor, if any Mark CHASIN
Second Inventor's signature Mark Chasin
Date May 23, 1996
Residence (city) Manalpan, (state or country) New Jersey
Citizenship United States of America
Post Office Address: 3 Wayne Court, Manalpan, New Jersey 07726, United States of America

3-00

Full name of joint Inventor, if any John Joseph MINOGUE
Third Inventor's signature John Joseph Minogue
Date MAY 21, 1996
Residence (city) Mount Vernon, (state or country) New York
Citizenship United States of America
Post Office Address: 33 East Grand Street, B-2B, Mount Vernon, New York 10552, United States of America NY

4-00

Full name of joint Inventor, if any Robert Francis KAIKO
Fourth Inventor's signature Robert F. Kaiko
Date May 23, 1996
Residence (city) Weston, (state or country) Connecticut
Citizenship United States of America
Post Office Address: 10 Norfield Woods Road, Weston, Connecticut 06883, United States of America CT

'295 - 55

MAIL ROOM JUN 10 1996 PAT. & TRADEMARK OFF.

1502

200.93311.CON

UNITED STATES PATENT AND TRADEMARK OFFICE

Re:

Application of:	Benjamin OSHLACK, et al.
Serial No.:	08/618,344
Filed:	March 19, 1996
For:	CONTROLLED RELEASE OXYCODONE COMPOSITIONS

JUL-25 1996

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

June 6, 1996

Sir:

Enclosed herewith are PTO-1449 forms listing the references cited during prosecution of parent U.S. Serial Nos. 08/467,584 and 08/081,302. Copies of the references were submitted by Applicant during prosecution of the '584 and '302 applications.

It is respectfully requested that these references be considered and made of record.

Respectfully submitted,
STEINBERG, RASKIN & DAVIDSON, P.C.

By _____
Clifford M. Davidson
Reg. No. 32,728

JUL 18 1996

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner of Patents and Trademarks, Washington, D.C. 20231" on June 6, 1996.
STEINBERG, RASKIN & DAVIDSON, P.C.
BY: _____

MAIL ROOM JUN 36 10 1996

Sheet 1 of 1

FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 200.93311.CON	SERIAL NO. 08/618,344
APPLICANT Benjamin OSHLACK, et al.	
FILING DATE March 19, 1996	GROUP 1602 JUL 25 1996

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA	4 8 6 2 5 9 8	8/89	Oshlack	424	470	
	AB	4 9 9 0 3 4 1	2/91	Goldie, et al.	424	484	
	AC	5 2 6 6 3 3 1	11/93	Oshlack, et al.	424	468	
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	TRANSLATION NO
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	
	AS	
	AT	

EXAMINER DATE CONSIDERED 9/96

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

'295 - 57

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/618,344	03/19/96	OSHLACK	B 200.933/CON

EXAMINER: WEBMAN, E

ART UNIT: 1502 PAPER NUMBER: 5

DATE MAILED: 10/23/96

15M1/1023

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/10/96

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7/10/96

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

* U.S. GPO: 1996-410-238/40050

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-13 of U.S. Patent No. 5,266,331. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant clams encompass those of '331 with regard to time and dose and visa versa with regard to peak plasma levels

Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 of U.S. Patent No. 5,508,042. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass those of '042 with regard to minimum plasma concentration.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to that which is disclosed. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Page 4, lines 19 - page 5, line 27 disclose mean minimum plasma concentration ranges. No broader ranges are disclosed. However, claims 1-10 claim any minimum plasma concentration, including zero. Thus, the specification is insufficient to support the breadth of the claims.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday-Friday from 9:00a.m. to 5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-2351.

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

Webman:css
October 9, 1996
October 18, 1996

Form PTO 948 (Rev. 10-94) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 618344

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

The drawings filed (insert date) 3/19/96 are
A. X not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.
B. ___ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this Notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   ___ Not black solid lines. Fig(s)___
   ___ Color drawings are not acceptable until petition is granted. Fig(s) ___
2. PHOTOGRAPHS. 37 CFR 1.84(b)
   ___ Photographs are not acceptable until petition is granted. Fig(s) ___
   ___ Photographs not properly mounted (must use brystol board or photographic double-weight paper). Fig(s)___
   ___ Poor quality (half-tone). Fig(s)___
3. GRAPHIC FORMS. 37 CFR 1.84 (d)
   ___ Chemical or mathematical formula not labeled as separate figure. Fig(s)___
   ___ Group of waveforms not presented as a single figure, using common vertical axis with time extending along horizontal axis. Fig(s)___
   ___ Individuals waveform not identified with a separate letter designation adjacent to the vertical axis. Fig(s)___
4. TYPE OF PAPER. 37 CFR 1.84(e)
   ___ Paper not flexible, strong, white, smooth, nonshiny, and durable. Sheet(s)___
   ___ Erasures, alterations, overwritings, interlineations, cracks, creases, and folds copy machine marks not accepted. Fig(s) ___
   ___ Mylar, velum paper is not acceptable (too thin). Fig(s) ___
5. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   21.6 cm. by 35.6 cm. (8 1/2 by 14 inches)
   21.6 cm. by 33.1 cm. (8 1/2 by 13 inches)
   21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)
   21.0 cm. by 29.7 cm. (DIN size A4)
   ___ All drawing sheets not the same size. Sheet(s)___
   ___ Drawing sheet not an acceptable size. Sheet(s) ___
6. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Paper size			
21.6 cm. X 35.6 cm. (8 1/2 X 14 inches)	21.6 cm X 33.1 cm. (8 1/2 X 13 inches)	21.6 cm. X 27.9 cm. (8 1/2 X 11 inches)	21.0 cm. X 29.7 cm. (DIN Size A4)
T 5.1 cm. (2")	2.5 cm. (1")	2.5 cm. (1")	2.5cm.
L .64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	2.5 cm.
R .64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.5 cm.
B .64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.0 cm.

   Margins do not conform to chart above.
   Sheet(s)___
   ___Top (T) ___ Left (L) ___Right (R) ___Bottom (B)
7. VIEWS. 37 CFR 1.84(h)
   REMINDER: Specification may require revision to correspond to drawing changes.
   ___ All views not grouped together. Fig(s)___
   ___ Views connected by projection lines or lead lines. Fig(s)___
   Partial views. 37 CFR 1.84(h) 2
   ___ View and enlarged view not labled separatly or properly. Fig(s)___
   Sectional views. 37 CFR 1.84 (h) 3
   ___ Hatching not indicated for sectional portions of an object. Fig(s)___
   ___ Cross section not drawn same as view with parts in cross section with regularly spaced parallel oblique strokes. Fig(s)___
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   ___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s)___
9. SCALE. 37 CFR 1.84(k)
   ___ Scale not large enough to show mechanism with crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s)___
   ___ Indication such as "actual size" or scale 1/2" not permitted. Fig(s)___
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
   ___ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s)___
11. SHADING. 37 CFR 1.84(m)
   ___ Solid black shading areas not permitted. Fig(s)___
   ___ Shade lines, pale, rough and blurred. Fig(s)___
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
   ___ Numbers and reference characters not plain and legible. 37 CFR 1.84(p)(l) Fig(s)___
   ___ Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(l) Fig(s)___
   ___ English alphabet not used. 37 CFR 1.84(p)(2) Fig(s)___
   ___ Numbers, letters, and reference characters do not measure at least .32 cm. (1/8 inch) in height. 37 CFR(p)(3) Fig(s)___
13. LEAD LINES. 37 CFR 1.84(q)
   ___ Lead lines cross each other. Fig(s)___
   ___ Lead lines missing. Fig(s)___
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
   ___ Sheets not numbered consecutively, and in Arabic numerals, beginning with number 1. Sheet(s)___
15. NUMBER OF VIEWS. 37 CFR 1.84(u)
   ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s)___
   ___ View numbers not preceded by the abbreviation Fig. Fig(s)___
16. CORRECTIONS. 37 CFR 1.84(w)
   ___ Corrections not made from prior PTO-948. Fig(s)___
17. DESIGN DRAWING. 37 CFR 1.152
   ___ Surface shading shown not appropriate. Fig(s)___
   ___ Solid black shading not used for color contrast. Fig(s)___

COMMENTS:

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ATTACHMENT TO PAPER NO. 5 REVIEWER [signature] DATE 7/11/96

FORM PTO-1083

Docket No. 200.93311.CON
Date: March 6, 1997

In the Application of: Benjamin OSHLACK, et al.
Serial No.: 08/618,344
Filed: March 19, 1996
For: CONTROLLED RELEASE OXYCODONE COMPOSITIONS

THE ASSISTANT COMMISSIONER FOR PATENTS
BOX FEE
Washington, DC 20231

RECEIVED
MAR 25 1997
GROUP 1500

Sir:
Transmitted herewith is an Amendment in the above-identified application.

[ ] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
[ ] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
[X] No fee for additional claims is required.
[ ] A filing fee for additional claims calculated as shown below, is required:

	(Col. 1) REMAINING AFTER AMENDMENT	(Col. 2) HIGHEST PREVIOUSLY PAID FOR		PRESENT EXTRA
FOR:				
TOTAL CLAIMS	*10	Minus -20	=	0
INDEP. CLAIMS	* 4	Minus -4	=	0
[ ] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

SMALL ENTITY RATE	FEE	OR	LARGE ENTITY RATE	FEE
x $ 11	$		x $	
x $ 40	$		x $	$
+ $130	$		+ $	$
TOTAL:	$	OR	TOTAL:	$0.00

* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Also transmitted herewith are:
[X] Petition for extension under 37 CFR 1.136 (in duplicate) for two months.
[ ] Other:

[X] A check in the amount of $500.00 is attached to cover:
[ ] Filing fee for additional claims under 37 CFR 1.16
[X] Petition fee for extension under 37 CFR 1.136 for two months
[X] Other: Terminal Disclaimer

[X] The PTO is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-4210. A duplicate copy of this sheet is enclosed.

[X] Any filing fee under 37 CFR 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
[ ] Any patent application processing fees under 37 CFR 1.17.
[X] Any petition fees for extension under 37 CFR 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Clifford M. Davidson
Registration No. 32,728
STEINBERG, RASKIN AND DAVIDSON P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

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6/ Req Ext of time (2mo)

200.93311.CON

UNITED STATES PATENT AND TRADEMARK OFFICE

AU-1502

RECEIVED
MAR 2 5 1997
GROUP 1500

Re:	Application of:	Benjamin OSHLACK, et al.	
	Serial No.:	08/618,344	
	Filed:	March 19, 1996	
	For:	**CONTROLLED RELEASE OXYCODONE COMPOSITIONS**	

PETITION FOR TWO MONTH EXTENSION UNDER 37 CFR 1.136(a)

Assistant Commissioner for Patents
Washington, D.C. 20231

March 6, 1997

Sir:

Applicants petition the Assistant Commissioner for Patents to extend the time for response to the Office Action dated October 23, 1996 for (2) months from January 23, 1997 to March 23, 1997.

A check for $390 covering the two (2) month extension fee is enclosed. If it is determined that any additional fees are due, the Assistant Commissioner is authorized to charge our Deposit Account No. 19-4210. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
STEINBERG, RASKIN & DAVIDSON, P.C.

By: _____
Clifford M. Davidson
Reg. No. 32,728

STEINBERG, RASKIN & DAVIDSON, P.C.
1140 Avenue of the Americas
New York, N.Y. 10036
(212) 768-3800

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to "Assistant Commissioner for Patents", Washington, D.C. 20231" on March 6, 1997.
STEINBERG, RASKIN & DAVIDSON, P.C.
BY: _____

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7/a

200.93311CON

Bet 4-4-97

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: E. Webman Art Unit: 1502

Re: Application of: Benjamin OSHLACK, et al.

Serial No.: 08/618,344

Filed: March 19, 1996

For: **CONTROLLED RELEASE OXYCODONE COMPOSITIONS**

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

March 6, 1997

Sir:

Responsive to the Office Action mailed October 23, 1996, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Page 1, line 4, after "June 18, 1993," insert --now U.S. Patent No. 5,549,912,--; and line 6, delete ", hereby incorporated by reference".

Page 6, line 18, delete "mμ-agonist" and insert therefor --μ-agonist--; and

Page 14, lines 18-19, delete "hydro-morphone" and insert therefor --oxycodone--.

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on March 6, 1997
STEINBERG, RASKIN & DAVIDSON, P.C.
BY: Diane Kelly

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IN THE CLAIMS:

a1

1. (Amended) A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone, based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 3 to about 120 ng/ml from about 10 to about 14 hours after administration every 12 hours after repeated dosing through steady state conditions , wherein said formulation [providing a desired analgesic effect] provides pain relief in said patient for at least [about] 12 hours after administration.

a2

8. (Amended) A method for substantially reducing the range in daily dosages required to control pain in human patients, comprising administering to a human patient an oral controlled release dosage formulation comprising from about 10 to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone form about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 3 to about 120 ng/ml from about 10 to about 14 hours after administration every 12 hours after repeated dosing through steady state conditions, wherein said formulation provides pain relief in said patient for at least 12 hours after administration.

9. (Amended) A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering to a human patient an oral solid controlled release dosage formulation comprising from about 10 mg to about 40 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of up to about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 3 to about 30 ng/ml from about 10 to about 14 hours after administration every 12 hours after repeated dosing through steady state conditions, wherein said formulation provides pain relief in said patient for at least 12 hours after administration.

10. (Amended) A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering to a human patient an oral solid controlled release dosage formulation comprising from about 40 mg to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 30 to about 120 ng/ml from about 10 to about 14 hours after administration after repeated dosing every 12 hours through steady state conditions, wherein said formulation provides pain relief in said patient for at least 12 hours after administration.

A2 concld,

REMARKS

Reconsideration of this application as amended is respectfully requested.

Claims 1 and 8-10 have been amended as described hereinbelow. Support for the amendments and new claims can be found throughout the specification.

In the Office Action mailed October 23, 1996, the Examiner rejected claims 1-10 under 35 U.S.C. § 112, first paragraph, taking the position that the specification is only enabling for dosage forms having a particular mean minimum plasma concentration. Applicants respectfully disagree with the Examiner's position. However, in the interest of expediting prosecution of this application, Applicants have amended the claims to recite the mean minimum plasma concentrations provided upon administration of the dosage forms. It is respectfully submitted that the inclusion of language reciting a mean minimum plasma concentration overcomes the Examiner's rejection. It is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be withdrawn. Applicants reserve the right to prosecute the rejected claims and any unclaimed subject matter in continuation applications.

The Examiner also rejected claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-13 of U.S. Patent No. 5,266,331. Claims 8-10 were rejected on the same grounds but as being unpatentable over claims 1 and 2 of U.S. patent No. 5,508,042.

To overcome the Examiner's obviousness-type double patenting rejection, Applicants submit herewith a Terminal Disclaimer disclaiming any portion of the patent term which extends beyond the '331 or '042 patents. It is respectfully submitted that the filing of the Terminal Disclaimer overcomes the Examiner's rejection of the claims based on obviousness-type double patenting. Applicants respectfully request withdrawal of the Examiner's rejections on this ground.

It is respectfully submitted that all rejections have been overcome and the application as amended is in condition for allowance. An early and favorable Notice of Allowance is respectfully requested.

A petition for a two month extension of time to respond the outstanding Office Action is submitted herewith, along with a check to cover the appropriate fee therefore.

It is submitted that no fee is due for entry of this amendment. If it is determined that any further fees are due, the Assistant Commissioner is authorized to charge Steinberg, Raskin & Davidson, P.C. Deposit Account No. 19-4210.

Respectfully submitted,
STEINBERG, RASKIN & DAVIDSON, P.C.

By: Clifford M. Davidson
Reg. No. 32,728

STEINBERG, RASKIN & DAVIDSON, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

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#8
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4/7/97

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT	Docket Number 200.93311.CON

In re Application of: Benjamin OSHLACK, et al.

Application No. 08/618,344

Filed: March 19, 1996

For: **CONTROLLED RELEASE OXYCODONE COMPOSITIONS**

. The owner>*<Euro-Celtique, S.A. of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent Nos. 5,266,331 and 5,508,042. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patents are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patents, as presently shortened by any terminal disclaimer, in the event that they later: expire for failure to pay a maintenance fee, are held unenforceable, are found invalid by a court of competent jurisdiction, are statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, have all claims canceled by a reexamination certificate, are reissued, or are in any manner terminated prior to the expiration of their full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submission on behalf an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney of record.

March 6, 1997
Date

Clifford Davidson
Signature

Clifford M. Davidson, Reg. No. 32,728
Typed or printed name

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.
☒ PTO suggested wording for terminal disclaimer was

☒ unchanged. ☐ changed (if changed, an explanation should be supplied).
>*Certification under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee.<

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/618,344	03/19/96	OSHLACK	B 200.93311CON

EXAMINER

15M1/0414

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

WEBMAN, E
ART UNIT | PAPER
1502 | 9

DATE MAILED: 04/14/97

NOTICE OF ALLOWABILITY

PART I.

1. ☒ This communication is responsive to PAPER # 8; FILED 3/10/97.
2. ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☒ The allowed claims are 1-10.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [ ] been filed in parent application Serial No. _____, filed on _____.
6. ☐ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- _ Examiner's Amendment
- _ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- _ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

T. D. APPROVED

EDWARD R. WEBMAN
PRIMARY EXAMINER
GROUP 1500

PTOL-37 (REV. 4-89) *

'295 - 69

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: Box ISSUE FEE
ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

15M1/0414

D G.

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED
08/618,344	03/19/96	010	WEBMAN, E	1502	04/14/97

First Named Applicant: OSHLACK, BENJAMIN

TITLE OF INVENTION: CONTROLLED RELEASE OXYCODONE COMPOSITIONS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 200.93311CON	424-468.000	L88	UTILITY	NO	$1290.00	07/14/97

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as yes, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown and notify the Patent and Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statementof Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.

III. All communications regarding this application must give application number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 05-96)(0651-0033) 3. PATENT AND TRADEMARK OFFICE COPY

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PART B—ISSUE FEE TRANSMITTAL

71-30 142-240

MAILING INSTRUCTIONS: This form should be used transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to addresses entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 5 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. See reverse for Certificate of Mailing, below.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

1. CORRESPONDENCE ADDRESS

15M1/0414

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)

INVENTOR'S NAME
Street Address
City, State and Zip Code
CO-INVENTOR'S NAME
Street Address
City, State and Zip Code
☐ Check if additional changes are enclosed

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Publishing Division
MAY - 5 1997
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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED
08/618,344	03/19/96	010	WEBMAN, E	1502	04/14/97

First Named Applicant: OSHLACK, BENJAMIN

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1 200.93311CON	424-468.000	L88	UTILITY	NO	$1290.00	07/14/97

3. Correspondence address change (Complete only if there is a change)

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.
1 Steinberg, Raskin & Davidson, P.C.
2
3

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Euro-Celtique, S.A.
(2) ADDRESS: (CITY & STATE OR COUNTRY) Luxembourg, Luxembourg

A. ☐ This application is NOT assigned.
☑ Assignment previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignment should be directed to Box ASSIGNMENTS.
PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☑ Issue Fee ☒ Advance Order - # of Copies 10
6b. The following fees should be charged to:
DEPOSIT ACCOUNT NUMBER 19-4210
(ENCLOSE A COPY OF THIS FORM)
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☒ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) (Date) 5/02/97

NOTE: This Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

Certificate of Mailing

Note: If this certificate of mailing is used, it can be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficent postage as first class mail in an envelope addressed to: Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

810 BL 05/29/97 08618344
1 142 1,290.00 CK
1 561 30.00 CK

on: May 2, 1997 (Date)
Sharon Meyer (Name of person making deposit)
(Signature)
May 2, 1997 (Date)

PTOL-85B (REV. 05-96) Approved for use through 05/31/99. OMB 0651-0033 1. TRANSMIT THIS FORM WITH FEE Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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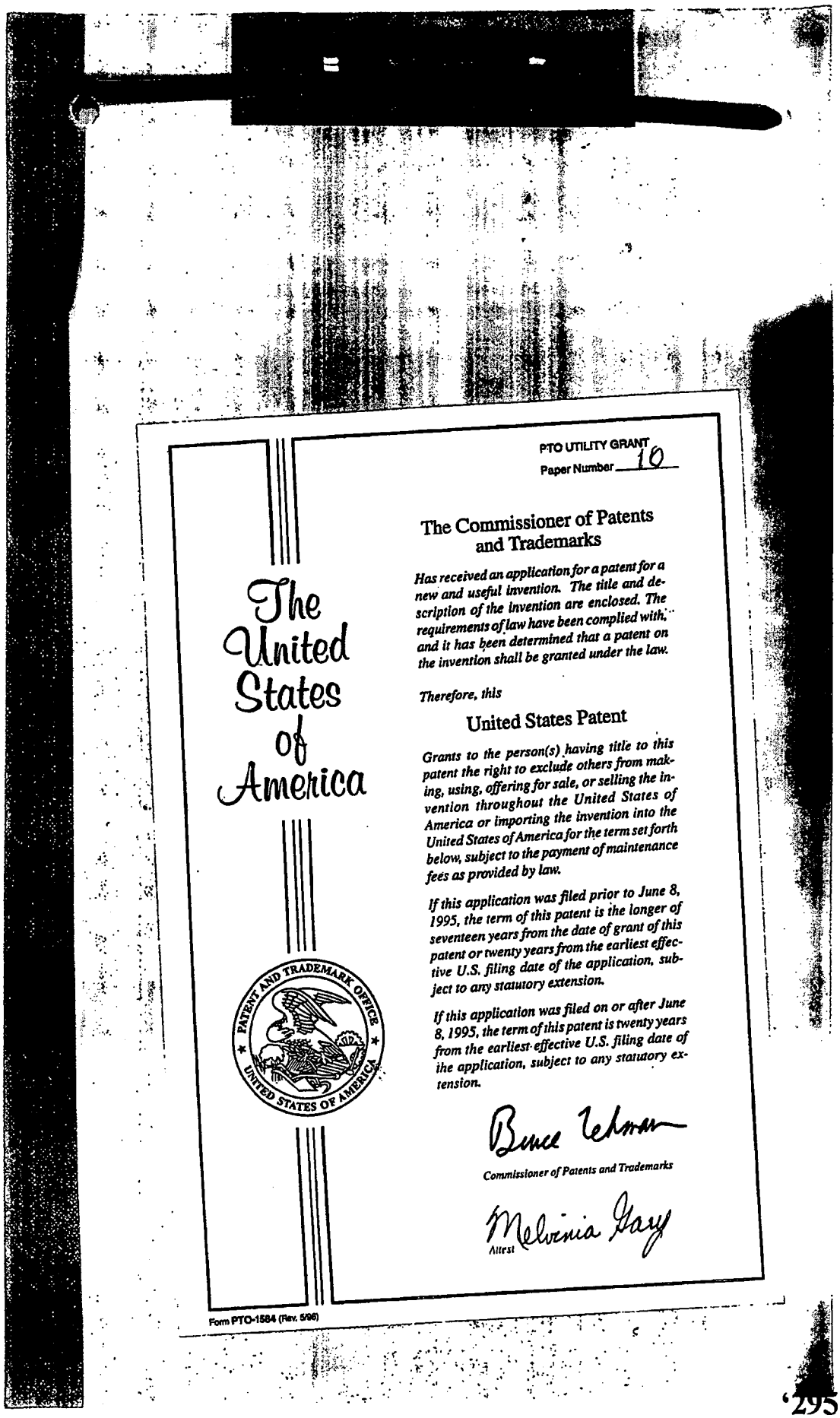

PTO UTILITY GRANT
Paper Number 10

The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

Bruce Lehman

Commissioner of Patents and Trademarks

Attest Melvinia Gary

Form PTO-1584 (Rev. 5/96)

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69652 U.S. PTO
07/28/97

1502

200.93311.CON

11/ Suppl Declaration

: UNITED STATES PATENT & TRADEMARK OFFICE

Re:	Application of:	Benjamin OSHLACK, Mark CHASIN, John J. MINOGUE, and Robert F. KAIKO	
	Serial No.:	08/618,344	AUG 1 4 1997
	Filed:	March 19, 1996	
	For:	**CONTROLLED RELEASE OXYCODONE COMPOSITIONS**	

Ret 8-20-97

SUPPLEMENTAL DECLARATION

Asst. Commissioner for Patents
Washington, D.C. 20231

July 24, 1997

Sir:

Enclosed please find an executed Supplemental Declaration and Power of Attorney form for the above-referenced patent application.

No fee is required. However, if any additional fees are deemed to be due at this time, the Commissioner is authorized to charge payment of the same to Deposit Account No. 19-4210. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
STEINBERG, RASKIN & DAVIDSON, P.C.

By
Clifford M. Davidson
Reg. No. 32,728

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on July 24, 1997
STEINBERG, RASKIN & DAVIDSON, P.C.
BY:

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Docket No.: 200.93311CON

SUPPLEMENTAL DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CONTROLLED RELEASE OXYCODONE COMPOSITIONS, the specification of which
X was filed on March 19, 1996 as Application Serial No. 08/618,344 and was amended on _____
(if applicable).
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is known to me to be material to the patentability of this application as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign and/or provisional application(s) for patent or inventor's certificate listed below and have also identified below any foreign and/or provisional application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR APPLICATIONS		Priority claimed		
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

07/800,549 (Application Serial Number)	November 27, 1991 (Filing Date)	U.S. Patent No. 5,266,331 (Status) (patented, pending, abandoned)
PCT/US92/10146 (Application Serial Number)	November 25, 1992 (Filing Date)	Pending (Status) (patented, pending, abandoned)
08/081,302 (Application Serial Number)	June 18, 1993 (Filing Date)	U.S. Patent No. 5,549,912 (Status) (patented, pending, abandoned)

And I hereby appoint Martin G. Raskin, Registration No. 25,642; Clifford M. Davidson, Registration No. 32,728; Brian Roffe, Registration No. 35,336; Leslye B. Davidson, Registration No. 38,854; James R. Crawford, Registration No. 39,155; Cary S. Kappel, Registration No. 36,561, Joshua L. Raskin, Registration No. 40,135; and John C. Todaro, Registration No. 36,036; my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Officeconnected therewith; correspondence address:
STEINBERG, RASKIN & DAVIDSON, P.C., 1140 Avenue of the Americas, New York, N.Y. 10036;
Telephone: (212) 768-3800; Fax: (212) 382-2124.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or **first**
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Inventor's signature Benjamin Oshlack

Date July 3rd 1997

Residence New York, N.Y. 10028

Citizenship Australia

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Full name of **second**
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Inventor's signature Mark Chasin

Date July 17, 1997

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Citizenship United States of America

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Full name of **third**
Inventor John Joseph MINOGUE

Inventor's signature John Joseph Minogue

Date July 18, 1997

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Citizenship United States of America

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Full name of **fourth**
Inventor Robert Francis KAIKO

Inventor's signature

Date July 7, 1992

Residence Weston, CT 06883

Citizenship United States of America

Post Office Address 10 Norfield Woods Road, Weston, CT 06883

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POSITION		ID NO.	DATE
CLASSIFIER		25	04-4-96
EXAMINER		313	4/22/96
TYPIST			6/11/96
VERIFIER		277	6-27
CORPS CORR.			
SPEC. HAND		351	6-6-96
FILE MAINT.			
DRAFTING			

INDEX OF CLAIMS

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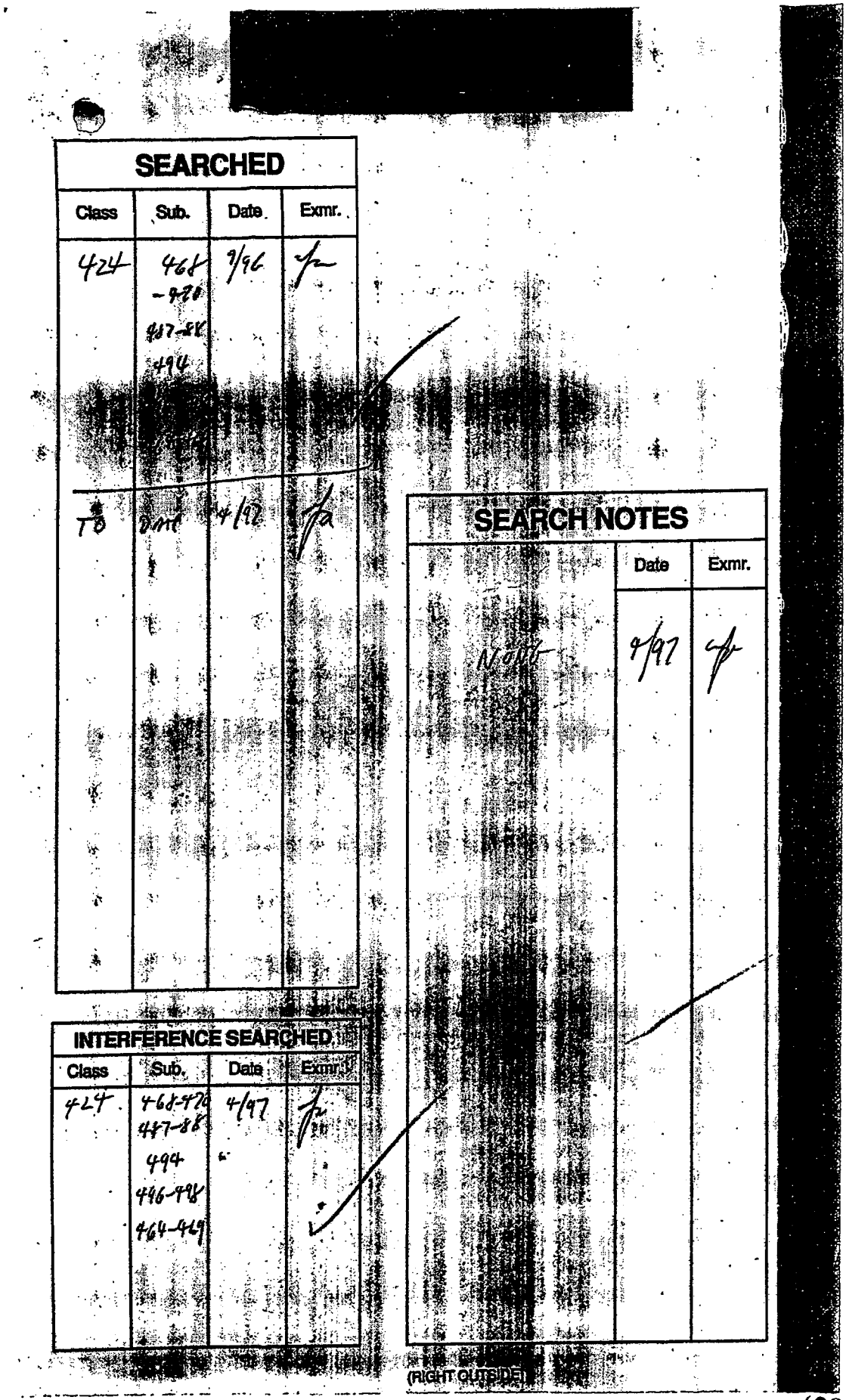

SEARCHED

Class	Sub.	Date	Exmr.
424	468 -470 487-88 494	9/96	JA
TD	DNC	4/97	JA

SEARCH NOTES

	Date	Exmr.
NONE	4/97	JA

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
424	468-470 487-88 494 496-498 464-469	4/97	JA

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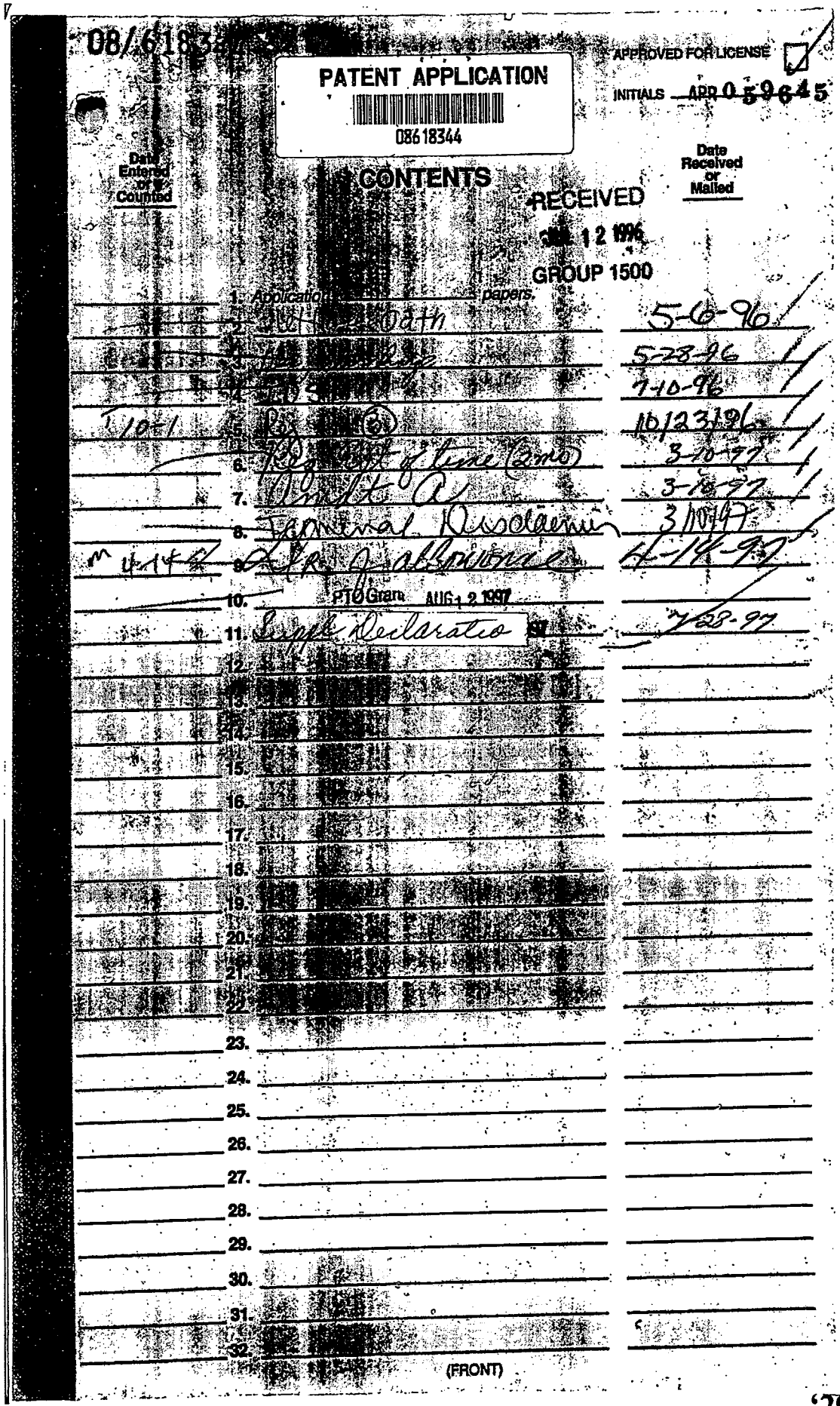

08/618344

PATENT APPLICATION

08618344

APPROVED FOR LICENSE

INITIALS APP 059645

CONTENTS

Date Entered or Counted

Date Received or Mailed

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1 2 1996

GROUP 1500

1. Application papers. 5-6-96
2. [illegible] 5-23-96
3. [illegible] 7-10-96
4. [illegible] 10/23/96
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6. Request for Extension (2mo) 3-18-97
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